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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, CAMTU TRAN	
ART UNIT	PAPER NUMBER
3772	

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07/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/839,643	KEREN ET AL.	
	Examiner	Art Unit	
	Camtu T. Nguyen	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 0909*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-51,59,60,68-73,78,84,86-90,92 and 97-108* is/are pending in the application.

4a) Of the above claim(s) *62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-51,59,60,68-73,78,84,86-90,92 and 97-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-21-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 3-9-09. Claims 1-48, 61, 63-67, 74-77, 79-83, 85, 91, 93-96, and 109-112 have been cancelled. Claims 49, 50, 59-60, 68-73, 78, 84, 86-90, 92, 97-108 have been amended.

PLEASE NOTE: Regarding cancelled claims 52-58, it is noted that these claims are not listed on the claim listing. Although they are cancelled, the claim listing must supply in ascending numerical order of all claims ever presented in the case. Therefore, please remember to add "Claims 52-58 (previously cancelled)" in your next actions to avoid a non-compliant amendment.

Response to Arguments

The Objections to claims have been withdrawn in view of applicant's remarks & amendment.

The 112, 2nd paragraph rejection to claims 49-50 (structure omitted) have been withdrawn in view of applicant's remarks & amendment.

The 112, 2nd paragraph rejection to claims 75 & 89 have been withdrawn (moot for claim 75 since it is now cancelled) in view of applicant's comments & amendment.

The 112, 2nd paragraph rejection to claims 49-50 (indefinite) have been withdrawn in view of applicant's remarks.

Regarding the 102(e) rejection, applicant remarked that the Bailey et al reference does not disclose a configuration which allow flow through a septum and can be used to regulate pressure between left and right heart chambers. In response, the Examiner respectfully disagrees. The Bailey et al's CC valve (40) can be used to regulate pressure differential (column 11 lines 13-23). Regarding the claimed limitation a shunt positioned within a septum, the Bailey et al reference discloses its CC valve (40) adapted for use in septal defects, which is known to be positioned within a septum. The Bailey et al CC stent valve (40) would allow flow through a septum & can be used to regulate pressure left & right heart chambers. Hence, Bailey rejection maintained at least based on the response presented.

Regarding the 102(b) rejection, applicant remarked that a shunt is defined as a hole/passage which moves/allows movement of fluid from one part of the body to another. In response, claims 49 & 50 do not require the shunt to move/allows movement of fluid from part of the body to another. Claims 49 & 50 recite a shunt positioned between a left atrium & a right atrium and anchored thereto via fixation elements. The King reference discloses a shunt (84, 94) positioning through a septum and anchoring the shunt (84, 94) to the septum using fixation elements (8, 9).

Regards the 103 rejection, the claims in those rejections are maintained for at least the reason(s) the Bailey et al is not patentably distinguished.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 49-51, 59-60, 68-71, 73, 78, 84, 86-87, 89, 90, 92, and 98-102 are rejected under 35 U.S.C. 102(e) as being anticipated by Bailey et al (U.S. Patent No. 6,458,153).

Bailey et al discloses in a stent valve (40) in the chamber-to-chamber (CC) configuration, the CC stent valve (40) comprising a valve (28) which opens allowing blood to flow through the stent valve (40) upon a pressure differential therebetween and would close by zero pressure differential therebetween (column 11 lines 13-23).

With regards to claims 49, 59, and 90 reciting the shunt device is positioned through a septum, Figures 12a & 12b illustrates the CC stent valve (40) is positioned through a septum mitral valve). Clearly, the Bailey et al reference discloses applicant's claimed invention.

With regards to claims 51, 86, 89, reciting allowing blood flow from the left atrium to the right atrium, such recitation is a mere functional recitation and a mere statement of intended use. The Bailey et al stent valve (40) would allow blood flow from one atrium to the next atrium when a pressure differential occur therebetween.

With regards to claim 84 & 102 reciting the valve implanted between two heart atria & in a transseptal hole, respectively, such recitations is a mere functional recitation and a mere statement of intended use. The Bailey et al stent valve (40) is capable of being between the two heart atria.

With regards to claims 60, 69, 71, and 73, the Bailey et al stent valve (40) comprising a valve (28) configured to allow passage of blood volume and is capable of gradual opening and/or closing.

With regards to claim 68, Figure 12a illustrates the stent valve (40) positioned in the mitral valve, a natural opening in the heart, which has an opening diameter of less than 5 mm.

With regards claim 70, Figures 12a & 12b illustrates the stent valve (40) has a length not substantially greater than a thickness of the septum.

With regards to claim 78, Figure 2 in the Bailey et al reference illustrates fixation elements (22) attached to opposite sides of the stent valve (40).

With regards to claims 87-88, under normal condition, pressure in the atrium is not more than 12 mm Hg when the mitral valve opens. With that in mind, when the Bailey et al stent valve (40) is positioned between the two heart atria, it would open when pressure is greater than normal condition of 12 mm Hg.

With regards to claim 92, when the Bailey et al stent valve device (10) is positioned in (CC) configuration, specifically, the atrium-to-atrium, the device (10) would allow for blood flow during pressure difference therebetween.

With regards to claim 99, the Bailey et al stent valve (40) would inherently close after draining of blood sufficient to reduce the mean atrium pressure by 5 mm Hg, as such drop approaches no pressure differential.

With regards to claims 98 & 100, the Bailey et al stent valve (40) configured to open during pressure differential.

With regards to claim 101, Figures 20a-20i illustrates the deployment of stent valve percutaneously.

The Bailey et al stent valve (40) would generate the same results desired by applicant's method claims.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 49 & 50 are rejected under 35 U.S.C. 102(b) as being anticipated by King et al (U.S. Patent No. 3,874,388).

King et al discloses a shunt (84, 94) implanted between a left atrium and a right atrium and anchored thereto via fixation elements (8, 9). The King et al shunt (84, 94) would generate the same result desired by applicant's claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 72, 88, 97, 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al (U.S. Patent No. 6,458,153) in view of Wolf et al (U.S. Patent No. 6,641,610).

Bailey et al discloses in Figures 7-11 a stent valve (40) in the chamber-to-chamber (CC) configuration, the CC stent valve (40) comprising elements in these claims but does not teach a sensor and a controller as recited in claims 97 & 103.

Wolf et al discloses in Figure 7 shunt conduit (34) comprising a valve (32) operative in conjunction with a sensor (30) senses/detects the signal output produced from the heart muscle and an actuator (36) opens the valve (32) based on the reading of the sensor (30).

Therefore, it would have been obvious to one of ordinary skilled in the art to utilize the sensor (30) & the controller (36), taught by Wolf et al, with Bailey et al's stent valve (40) as such would regulate the stent valve (40) in order to prevent any potential back flow in the heart atria.

With regards to claims 81-83, the Wolf et al discloses a display in the form of an electrocardiogram machine indicating the heart activities, thus, indicting the condition of the valve involved.

With regards to claims 72, Wolf et al discloses a hydrodynamic/electric pump (column 7 lines 4-7), for controlling the valve, of which is well known in the art to be outside of the patient's body.

With regards to claim 88, Wolf et al discloses a hydrodynamic/electric pump (column 7 lines 4-7), for controlling the valve et al valve would open to relief pressure built in the atrium flow when pressure is above 12 mmHg.

Claims 104-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al (U.S. Patent No. 6,458,153)/Wolf et al (U.S. Patent No. 6,641,610), presented above, and further in view of Cosman (U.S. Patent No. 4,787,886).

Bailey et al/Wolf et al, presented above, discloses a stent valve (40) in the chamber-to-chamber (CC) configuration, the CC stent valve (40) comprising elements in these claims including a sensor and a controller but does not teach the sensor comprises a pressure.

Cosman discloses a shunt valve system comprising a pressure sensor. Therefore it would have been obvious to one skilled the art to use the sensor that senses/detects a pressure, taught by Cosman in place of Bailey et al's sensor for purposes of sensing/detecting a pressure in the patient's heart.

With regards to claims 106-108, the Bailey et al valve would open to relief pressure built in the atrium flow when pressure is above 20 mmHg, a pressure mark that is considered high for diastole cycle.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772